Quality Metrics and Risk Management with High Risk Radiation Oncology Procedures

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In Search of a QA Usability Metric
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Disclosure of Conflict of Interest

None except AAPM waived day registration fee
Topics
Introduction
AAPM Summer School 2013
Review of Northwestern Data
Risk Categories or Scales
Examples of High Risk Procedure Catastrophic Failures
Time Out as a QA Usability Metric for High Risk Procedures
Conclusions

Learning Objectives

• Provide an overview and the need for QA usability metrics: Different cultures/practices affecting the effectiveness of methods & metrics.
• Show examples of quality assurance workflows, Statistical process control, that monitor the treatment planning and delivery process to identify errors.
• To learn to identify and prioritize risks and QA procedures in radiation oncology.
• Try to answer the question: Can a quality assurance program aided by quality assurance metrics help minimize errors and ensure safe treatment delivery?
• Should such metrics be institution specific?
• A discussion of TG–100’s efforts was a central feature of the summer school.

• Optimizing the care pathway, a.k.a. the process map, is another opportunity for enhancing not only quality and safety, but also efficiency.

• Some relevant techniques were discussed throughout the summer school.

• In all the stages of radiotherapy there is potential to cause a major harm to the patient.

• Physicists play an important role in identifying and minimizing these risks.

Device-centric vs Process-centric Quality Management

• Traditionally, the radiation oncology physics community has had a largely device-centric perspective.

• This has changed in recent years with the recognition that many of the safety and quality issues have significant human factors content.

• The AAPM’s Task Group 100 is working to bring objectivity to quality management programs, covering both equipment and people, with the example being IMRT (Huq et al. 2008).
Financial Reality & Time Commitment

- It is worth placing the proposed interventions and measures in the context of the financial reality of today's health care.
- While a full-blown FMEA or root cause analysis (RCA) could be expensive to perform, it is not hard to devise shortcuts and expedited approaches, e.g., do a simple analysis on your own without a team, which will bring benefits.
- The first hurdle is to develop a familiarity and comfort level with these error management techniques that are foreign to most of us.
- Recent documents, such as “Safety is No Accident,” suggest measures for enhancing safety and quality that have minimal resource requirements (Zietman, Palla, and Steinberg 2012).
- For example, “no interruption zones,” which are widely considered to be effective, require some leadership but little else.

Early Efforts & Emerging Developments in Process-centric Quality Management

- The first major efforts to systematically address error mitigation in a radiation therapy process were AAPM’s guidance documents for clinical brachytherapy published in the late 1990s.
- Meanwhile, the 1998 TG–59 Report High dose-rate brachytherapy treatment delivery (Kubo et al. 1998) serves as an extended example of applying TG–56 principles to the HDR brachytherapy domain.

TG 56 & TG 59 – Early Pioneers

- Both reports accepted that low-probability human errors—including measurement errors, communication failures, and transcription errors—must be detected and corrected to avoid catastrophic treatment delivery errors.
- This approach was designed to complement the prescriptive QA program outlined by TG 56 for HDR and LDR brachytherapy devices.
- These reports attempted to lay out a general QM system design process that could be adapted to many different kinds of clinical procedures.
- Reports 56 and 59 proposed that the QA program was not a separate activity imposed upon the clinical workflow, but that such processes should be prospectively designed from the ground up with the goal of making them robust to error propagation by building QC and QA checks into their basic structure.
QA Areas of Focus in Radiation Oncology

- Machine QA
- Process QA
- Focus on Daily Treatment Delivery
- Adequate focus on commissioning

QA Procedures

- QA procedures are needed to ensure equipment are functioning according to acceptable tolerances
- Also needed are procedures and workflow to ensure accurate planning & delivery of treatments
- Physicists play an important role in both of these steps
What Quality Means to Us
Delivering care that is effective, safe, coordinated, timely and convenient.

To find out if we are achieving quality care, we constantly measure our healthcare performance by collecting hundreds of quality measures.

We make our Quality Ratings public to let know how we measure up to national healthcare quality comparisons.
Good Catch Award

Jeff, Julie and Anna were recognized at this month’s M&M conference for a great catch they were responsible for last month.

In May, Julie was performing a daily, routine Cone Beam CT scan on a patient prior to their radiation treatment. This scan is generally only used for to center verification and not used for diagnostic purposes. However, Julie noticed that the patient’s lungs appeared hazy with mediastinal changes. Julie, along with Jeff Levinson and Anna Pecherczyk, brought this to the attention of the attending physician. After reviewing the image, the patient was immediately sent for an X-ray, follow-up CT, and bronchoscopy where a mucus plug was identified. The patient was then sent for surgery.

Margaret, the program manager from Patient Safety and Quality Strategies, stated that this was “one of the ‘best’ good catches that Patient Safety has seen in a while.”

Great job Julie, Jeff and Anna! Our patients are so lucky to have such an amazing team taking care of them each and every day. Thank you for going above and beyond to care for the patients we treat. This is truly an example of “Every Patient Matters.”

The Profession

A Comprehensive Quality Assurance Program for Personnel and Procedures in Radiation Oncology: Value of Voluntary Error Reporting and Checklists

John A. Kalapurakal, MD,1 Aleksandar Zaffirovski, MBA, RT,1 Jeffrey Smith, BS,1 Paul Fisher, AS, RT,2 Vythilingam Sathianesan, PhD,3 Cynthia Bernard, MBA, HCSS, CPHI,4 Alfred W. Radmacher, PhD,1 Nick Rave, MS,3 and Bharat B. Mittal, MD4

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Workflow and Quality Checks
Key Components of Our Safety Program

• Time outs
• Checklists

Timeouts and Checklists

Time Out as a Quality Metric for High Risk Procedures

The Wrong way to do a Time Out

Successful Time Out Process

From: Spruce & Ogg, Prevention of Wrong Site Surgery
**Time Outs**

**Radiation Oncology High Risk Procedures**

- External beam therapy => IMRT
- Brachytherapy => HDR & LDR
- Radiosurgery
- SBRT
- SART
- IORT

**Radiotherapy Risk Profile**

- Through published literature review identified risk areas in the radiotherapy treatment process
- Specifically targeted interventions to improve patient safety
Potential Risk Areas in Radiotherapy Treatment

<table>
<thead>
<tr>
<th>Category</th>
<th>Frequency</th>
<th>Severity</th>
<th>Probability</th>
<th>IFU</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>Check</td>
</tr>
<tr>
<td>Procedure</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>Review</td>
</tr>
<tr>
<td>Staff</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>Training</td>
</tr>
<tr>
<td>Environment</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>Clean</td>
</tr>
<tr>
<td>Dosimetry</td>
<td>1</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>Calibrate</td>
</tr>
</tbody>
</table>

French Risk Scale

- Important to Categorize Near Miss Events using a Risk Scale
- Helps in identifying and minimizing major risks that can lead to catastrophic failures

Definition of Quality Metrics

- The Business Dictionary defines the word metrics as "standards of measurement by which efficiency, performance, progress, or Quality of a plan, process, or product can be assessed."
- Quality metrics is applied to measuring whether or not a given process will produce products and services that meet quality standards.
Examples of Quality Metrics & Effectiveness

**Quality Control Quantification (QCC): A Tool to Measure the Value of Quality Control Checks in Radiation Oncology**

Eric C. Ford, PhD, M. Stephan Terezakis, MD, Annette Seurans, MD

Summary

Clinical Investigation: Quality Assurance

The combination of checks with highest effectiveness (from 15 common QC checks) includes:

- physics plan review
- physician plan review
- EPID-based portal dosimetry
- radiation therapist timeout
- weekly physics chart check
- use of checklists
- port films
- SSD distance checks

Examples of High Risk Procedure Catastrophic Failures

- HDR
- Linac Radiosurgery
- Gamma Knife Radiosurgery
- LDR Prostate Brachytherapy
- EBRT => IMRT & SBRT
Medical Events in Brachytherapy

### Table 1: Causes of events (left) and type of dose delivery (right)

<table>
<thead>
<tr>
<th>Causes of event (No. of events)</th>
<th>Type of dose delivery (No. of events)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication issues (19)</td>
<td>LDR (7)</td>
</tr>
<tr>
<td>Equipment malfunction (23)</td>
<td>LDR (6)</td>
</tr>
<tr>
<td>Human error (97)</td>
<td>LDR (5)</td>
</tr>
<tr>
<td>Lack of training (12)</td>
<td>LDR (4)</td>
</tr>
<tr>
<td>Miscellaneous (5)</td>
<td>LDR (3)</td>
</tr>
<tr>
<td>Other (5)</td>
<td>LDR (2)</td>
</tr>
</tbody>
</table>

Numbers in parentheses indicate the number of events reported. LDR, high dose rate; LDR, low dose rate; RP, radionuclide.

### Medical Event (misadministration)
- Total delivered dose differs from the prescribed dose by 50% or more.
- The delivered dose, as a simple fraction, differs from the prescribed fractional dose by 10% or more.
- Other NR: excessive dose to normal tissue(s), wrong patient, wrong site, wrong isotope, wrong modality, or use of leaking sources.

10 CFR 20.1945
Medical Events in Brachytherapy

Medical events in HDR Brachytherapy (1999-2012)
- 121 errors were reported.
- Majority of errors: targeting errors or wrong treatment site.
- 167 errors were related to dose measurement, planning, or treatment.

HDR ME - Applications

Types of errors in HDR
- Targeting errors or wrong treatment site (27.6%): incorrect length, step size, insertion, or dislodgement.
- Treatment planning errors (21.1%): wrong dose, isocenter, activity, or factor.
- Treatment delivery errors (16.5%): wrong plan, dwell times, bladder distension.
- Source retraction problems (10%)
- Other (25.8%)

MEs in Prostate Seed Implant (1999-2012)
- Total number of ME implants: 500 (0.01%)
- Included: wrong implant, wrong seed, use of wrong isotope, incorrect planning, or incorrect treatment.
- Incorrect source strength, incorrect dose rate constant, or other planning errors (10%)
- Needled seed implantation, or excessive dose to normal tissue (8%)
- Discrepancy in dose to target (10%)
- Pinnacle (20%)
- Varian (15%)
- Other parameters used: dose, time, ‘spike’

Never Events

Ensuring correct patient, correct treatment, correct procedure in Radiation Therapy Treatment
A reduction in error rates by a factor of three was realized.
**LDR Prostate Brachytherapy**
- Correct activity for monotherapy vs boost
- Zero base image

**LDR GYN Brachytherapy**
- Correct activity for Cs sources in plan
- Sources loaded correctly

**HDR Brachytherapy**
- Correct cylinder

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**Gamma Knife Radiosurgery**
- Correct plan transmitted
- Correct isodose chosen
- Correct treatment site\side => Trigeminal

**External Beam Radiotherapy**
- IMRT => open fields
- Wedge => missing

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### Procedure Summary

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No of Procedures</th>
<th>Medical Events</th>
<th>Near Miss Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma Knife</td>
<td>479</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>HDR Brachytherapy</td>
<td>157</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>LDR Brachytherapy - Prostate</td>
<td>15</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>LDR Brachytherapy - GYN</td>
<td>50</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>IORT</td>
<td>90</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>SBRT</td>
<td>502</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

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**January 1, 2012 to June 15, 2014**

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**Barriers to Effective Time Outs**
- Time constraints
- Staffing
- Culture
- Lack of communication
- Education\Training
- “Mindfulness” => Recognizing the risk
- Perception of importance
Incident Learning Systems

- Valuable for tracking near miss events
- Paper based to Electronic

Dosimetry T\O Compliance

Accurate Charts
Conclusions

• Time outs are good tools to mitigate catastrophic failures
• Identify key steps to check which can lead to catastrophic failures
• Quality of time outs is critical
• Developing a culture of safety is very important
• Audit to maintain quality
• Continuous communication between caregivers is essential

Questions?

• Is Time Out a Quality Metric?
• How can we measure it?
• How can we use this simple tool as an effective Quality Metric to eliminate catastrophic errors in radiation oncology?

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